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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,197	02/12/2002	Christiane Boie	Mo-6952/LeA 33,859	1635.

34469 7590 06/20/2003

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EXAMINER

MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,197

Applicant(s)

BOIE ET AL.

Examiner

Thomas McKenzie Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-12,14 and 15 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4&7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to an application filed on 2/12/02. There are fourteen claims pending and fourteen under consideration. Claims 4-10 are compound claims. Claim 11 is a composition claim. Claims 1-3 and 12 are use claims. Claims 14 and 15 are synthesis claims. This is the first action on the merits. The application concerns some amino salicylic acid amide compounds, compositions, and uses thereof.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While Applicants have provided a list of allowed alkyl substituents for radical R⁴ in lines 6-13, page 5, there is no such definition given for radicals R⁶ or Z. Lines 22-27, page 5 and lines 2-9, page 6 say the alkyl groups may be substituted but substituted by what?

3. Claims 4, 7-12, 14, and 15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 4, radicals R¹⁴,

R¹⁶, Z¹, and R²⁰ all maybe "optionally substituted alkyl". Optionally substituted by what?

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for controlling fungi, does not reasonably provide enablement for controlling all organisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. A broad reading of organisms able to cause damage would include human saboteurs, rodents, rabbits, and birds, which are not what is intended.

“The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims”, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. a) Determining if any particular damaging organism would be

controlled would require synthesis of the each compound to be tested and subjecting an unknown list of organisms a differing application rates to learn if the organisms were controlled. This is a large degree of experimentation. b) The direction concerning the organism to be controlled is found in lines 26-29, page 13 that merely states Applicants' intent to control all organisms. Lines 5-11, page 40 and the passage spanning line 20, page 30 to line 30, page 32 list a large number of micro-organisms Applicants intent to treat. Possible formulations are given in the passage spanning line 31, page 32 to line 5, page 34. Application rates are listed in lines 21-30, page 40. A 100,000-fold range of application rate is taught. Since testing results are given for only four of the millions of compounds of Formula (I), how is the skilled farmer to know how much to apply? c) There are sixteen working examples of use of four compounds of formula (I) against four fungi. d) The invention is directed toward control of fungi and is therefore physiological in nature.

e) The state of the art is summarized in lines 4-11, page 1 of the specification. f) The artisan using Applicants invention to control fungi would be a farmer with high school training in agriculture and several years of experience. g) It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally

considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). h) The breadth of the claims includes all of the millions of compounds of formula I as the presently unknown list of organisms embraced by claim 1.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

5. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for controlling fungi does not reasonably provide enablement for all pests. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. A broad reading of pests would include rodents, rabbits, and birds, which are not what is intended.

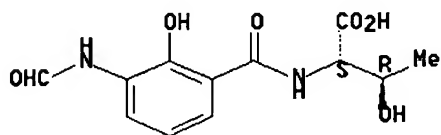
Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

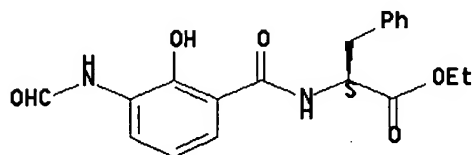
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by van Tamelen (JACS, ref AT). The compound shown below fits formula (I-a) with $R^{11} = R^{12} = R^{16} = R^{21} = \text{hydrogen}$, $R^{13} = \text{the first group}$, $R^{20} = \text{the ethyl group substituted by hydroxyl}$, and $A = \text{oxygen}$. It has Registry Number 34999-22-9 and is found in the diagram on the right side of page 1639 of the reference. It is compound II.

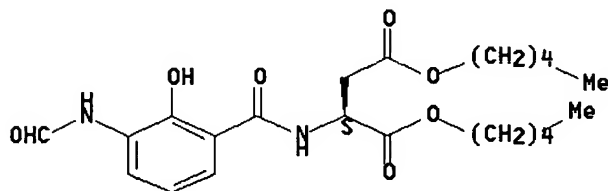


7. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Batra (Journal of Biological Chemistry). The compound shown below fits formula (I-a) with $R^{11} = R^{12} = R^{21} = \text{hydrogen}$, $R^{13} = \text{the first group}$, $R^{20} = \text{the methyl group substituted phenyl}$, $R^{16} = \text{ethyl}$, and $A = \text{oxygen}$. It has Registry Number 34999-31-0 and is found in Table I, page 7127 of the reference. It is compound 12.

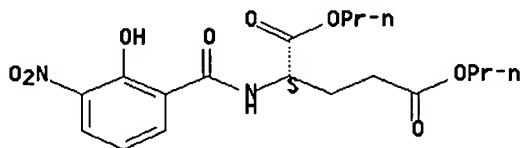


8. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokutake (BBA, ref AR). There are eleven compounds in this reference that

anticipate Applicants' compound claims. For example, the compound shown below fits formula (I-a) with $R^{11} = R^{12} = R^{21} = \text{hydrogen}$, $R^{13} = \text{the first group}$, $R^{14} = \text{the methyl group substituted by the alkoxycarbonyl group pentyloxycarbonyl}$, $R^{16} = \text{pentyl}$, and $A = \text{oxygen}$. It has Registry Number 148174-12-3 and is found in Table II of page 265 of the reference. It is compound 19. Other relevant compounds are 13-18 and 20-23.

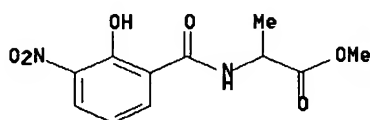


9. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Tokutake (Biochim. Biophys. Acta). The compound shown below fits formula (IVa) with $R^{12} = R^{21} = \text{hydrogen}$, $R^{13} = \text{the first group}$, $R^{14} = \text{the ethyl group substituted by the alkoxycarbonyl group propyloxycarbonyl}$, $R^{16} = \text{propyl}$, and $A = \text{oxygen}$. It has Registry Number 156272-68-3 and is found in Figure I of page 272 of the reference. It is compound 25.



10. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Wu (Biochim. JHC, ref AS). There are three compounds that anticipate Applicants'

claim. The compound shown below fits formula (IVa) with $R^{12} = R^{21} = \text{hydrogen}$, $R^{13} = \text{the first group}$, $R^{14} = R^{16} = \text{methyl}$, $A = \text{oxygen}$. It has Registry Number 35748-40-4 and is found in the scheme of page 989 of the reference. It is compound VI. Others are VII and X.



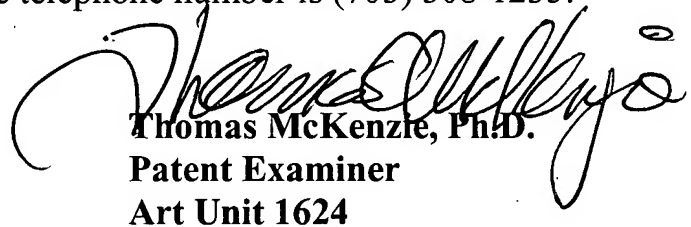
11. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Tokutake (BBA, ref AR). The reaction diagramed as the last step in Scheme 1 on page 263 in this reference that anticipates Applicants' synthesis claim of process (a). The acylating agent HCOOH fits formula (III) with $R^{11} = \text{hydrogen}$ and $X^1 = \text{hydroxyl}$. The reaction auxiliary is DCC. The diluent is toluene.

Allowable Subject Matter

12. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 7-9, 11, and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

13. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for before final amendments is (703) 872-9306. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, you can reach the Examiner's supervisor, Mukund Shah at (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.


Thomas McKenzie, Ph.D.
Patent Examiner
Art Unit 1624

TCMcK
June 18, 2003